

Remarks:

Reconsideration of the application is requested.

Claims 1 to 10, 17, 18, and 21 to 31 are now in the application. Claims 1 to 10, 17, 18, and 21 to 31 are subject to examination. Claims 21 to 31 have been added. Withdrawn claims 11 to 16 and 19 to 20 have been canceled to facilitate prosecution of the instant application. Applicants reserve the right to file a divisional application for these canceled claims.

In item 1 on page 2 of the above-identified Office action, claim 1 has been rejected as being indefinite under 35 U.S.C. § 112, first / second paragraph. More specifically, the Examiner states that "Applicant says that the retainer 'has a length of *at least* approximately π times the distance between the arms . . .'. It is unclear whether the 'at least' is further limiting the word 'approximately' or if Applicant is saying that the retainer's length can be any amount greater than $3.1415 \times$ (the distance between the arms)."

The "at least" in claim 1 applies to the word "approximately" and use of approximately means that the length of the retainer can be a little less than $3.1415 \times$ (the distance between the arms).

It is accordingly believed that the specification and the claims meet the requirements of 35 U.S.C. § 112, second paragraph.

In items 3 to 6 on pages 3 to 4 of the above-identified Office action, claims 1 and 5 to 10 have been rejected as being fully anticipated by Wilson (U.S. 3,851,359) under 35 U.S.C. § 102.

In items 7 to 10 on pages 4 to 5 of the above-identified Office action, claims 1, 2, 4, and 5 have been rejected as being fully anticipated by McQuilkin et al. (U.S. 5,575,802; hereinafter "McQuilkin") under 35 U.S.C. § 102.

In items 11 to 12 on page 5 of the above-identified Office action, claims 1, 5, and 6 have been rejected as being fully anticipated by Alessi et al. (U.S. 2,246,495; hereinafter "Alessi") under 35 U.S.C. § 102.

In item 13 on pages 5 to 6 of the above-identified Office action, claims 17 and 18 have been rejected as being fully anticipated by DiGiovanni et al. (U.S. 4,430,997; hereinafter "DiGiovanni") under 35 U.S.C. § 102.

As will be explained below, it is believed that the claims were patentable over the cited art in their original form and, therefore, the claims have not been amended to overcome the references.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Claims 1 and 17 call for, *inter alia*, a surgical clip, including:

a bridge connecting first and second arms to form a substantially U-shaped structure; and

at least one deformable retainer extending from one of the arms, the retainer having a length of at least approximately n times the distance between the arms when the arms are substantially parallel.

New claim 21 is similar and calls for, *inter alia*, a surgical clip, including:

a bridge connecting first and second arms to form a substantially U-shaped structure with the arms being substantially parallel to one another; and

at least one deformable retainer extending from one of the arms, the retainer having a length equal to a multiple of a distance between the arms, the multiple being approximately equal to n .

New claim 22 is similar and calls for, *inter alia*, a surgical clip, including:

a bridge connecting first and second arms to form a substantially U-shaped structure; and

at least one deformable retainer extending from one of the arms and having a deformable portion, the deformable portion having a length of at least approximately n times the distance between the arms when the arms are substantially parallel.

Wilson discloses a safety pin "of the type normally used for fastening to fabrics and clothing . . . such as securing diapers on babies." Wilson at col. 1, lines 5 to 9. Wilson's safety pin is made to close easily. See Wilson at col. 3, lines 15 to 33. However, to remove the safety pin, the frangible portion 10d must be broken -- rendering the remaining pin parts unusable. See Wilson at col. 3, lines 33

to 40. Wilson does not disclose or suggest *surgical* use of Wilson's 1973 variation of the commonly used safety pin.

The Examiner states that the structure analogous to the first arm is leg portion 10a, to the second arm is leg portion 10b, and to the bridge is transition bend 10c. The Examiner further states that Wilson's deformable retainer is the head 11 of the safety pin. As described with respect to FIGS. 5 and 6 in Wilson, the only aspect of the safety pin that deforms in the head 11 is the resiliently deformable flap 11c -- unless the frangible portion 10d (not a part of the head 11) is deemed to be counted as a deformable retainer, which, applicants believe, is not a viable alternative.

The Examiner admits that the distance between the two parallel arms 10a, 10b is 9.5 mm as measured in the drawings. The resiliently deformable flap 11c is (without the need for measurement) not greater than the distance between the arms 10a, 10b. Therefore, the flap 11c cannot be considered as having "a length of at least approximately n times the distance between the arms when the arms are substantially parallel" as set forth in claim 1 (see also claims 17, 21, and 22).

The Examiner indicates that the length of the retainer 11 (which is the pin head) is 1.85 mm. Accordingly, the retainer 11 cannot be considered to be more than three times the 9.5 mm arm distance.

Clearly, Wilson does not show a surgical clip as recited in claims 1, 17, 21, or 22 of the instant application.

McQuilkin discloses a medical clip "suitable for sexual sterilization." See Abstract and col. 1, lines 3 to 6. FIG. 1 illustrates the medical clip in the opened position and FIGS. 2 and 3 illustrate the clip in the closed and closed-and-fastened positions, respectively.

Because the clip is to be clamped upon a Fallopian tube or vas deferens to effect occlusion, direct contact between the silicone rubber lining 18, 20 of the jaws 12, 14 is required. In other words, the distance between the jaws 12, 14 is equal to **zero**. Therefore, the McQuilkin retainer cannot have a "length of at least approximately n times the distance between the arms when the arms are substantially parallel" as set forth in claims 1 (see also claims 21 and 22).

Further, the jaws 12, 14 are not parallel when in the non-applied (open) position and are parallel only when the

McQuilkin clip is in the occluding (closed) position.

Accordingly, McQuilkin does not and cannot teach two arms having a "distance between the arms when the arms are substantially parallel" to one another as set forth in claims 1, 17, 21, and 22.

Clearly, McQuilkin does not show a surgical clip as recited in claims 1, 17, 21, or 22 of the instant application.

Alessi discloses a variation of a common safety pin.

The Examiner, on page 5, states "Alessi discloses a clip *capable of use in surgery. . .*" Upon review of the Alessi specification, the only mention of use for the safety pin relates to the same use that is made by a "safety pin of the type in common use." Alessi at page 1, lines 4 to 5 and 22 to 24 left column, for example. Nowhere does Alessi disclose or suggest *surgical* use of Alessi's 1938 variation of the commonly used safety pin.

Alessi discloses a device for retaining the swiveling pin member 10 with respect to the tubular guard 15. Each mention of the pin member 10 in the patent describes the member 10 as being rigid. For example, page 1, lines 4 to 9 right column, provides that only "abnormal distortion by exceptional stress

will be required to divert the pointed end of the pin out of range of the guard." Page 1, lines 17 to 19 right column, provides "a relatively rigid pin member to achieve substantial inherent resistance to flexure." Simply put, the Alessi pin member 10 is not flexible, let alone deformable.

The tubular guard 15 is not envisioned to bend or deform. The only aspect of the Alessi safety pin that does deform is the torsional spring 21. This spring 21 has a length that is, in some embodiments (FIGS. 1, 3, 4), barely equal to the distance between the parallel first and second tubular portions 16, 17. FIG. 5 shows the spring 40 slightly greater than the distance between the parallel first and second tubular portions 16, 17. In no way does either spring 21, 40 have "a length of at least approximately n times the distance between the arms [16, 17] when the arms are substantially parallel" as set forth in claims 1, 21, or 22. Even if one could consider the first portion 16 as part of a deforming retainer, the combined distance is no greater than twice the distance between the arms 16, 17.

Clearly, Alessi does not show a surgical clip as recited in claims 1, 17, 21, or 22 of the instant application.

DiGiovanni discloses a multiple clip applier used to apply clips like those in McQuilkin. See, in particular, FIG. 2A of DiGiovanni. Therefore, all of the arguments with respect to McQuilkin are applicable to distinguish DiGiovanni and are hereby incorporated by reference. It is particularly noted that the clips are set "to ligate a vessel," are set "about the vessel to be ligated" and/or are "set to ligate the vessel." See DiGiovanni at col. 1, line 15, col. 2, lines 5, 31, and 40, respectively. Thus, the arms have a zero distance when parallel.

Clearly, DiGiovanni does not show a surgical clip as recited in claim 1, 17, 21, or 22 of the instant application.

It is accordingly believed to be clear that none of the references, whether taken alone or in any combination, either show or suggest the features of claims 1, 17, 21, or 22. Claims 1, 17, 21, and 22 are, therefore, believed to be patentable over the art. The dependent claims are believed to be patentable as well because they all are ultimately dependent on claims 1, 17, or 22.

Finally, claims 21 to 31 have been added. Independent claims 21 and 22 are variations of independent claim 1 and find support in the specification of the instant application. New

dependent claims 23 to 31 are based upon original claims 2 to 10. Thus, no new matter has been added.

In view of the foregoing, reconsideration and allowance of claims 1 to 10, 17, 18, and 21 to 31 are solicited.

In the event the Examiner should still find any of the claims to be unpatentable, counsel would appreciate receiving a telephone call so that, if possible, patentable language can be worked out.

If an extension of time for this paper is required, petition for extension is herewith made.

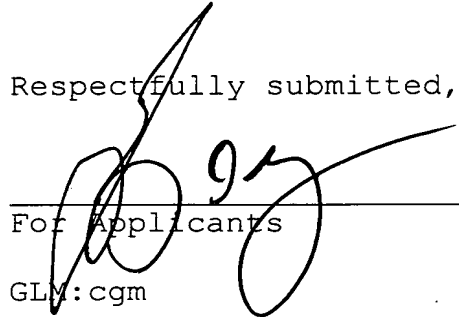
The extension fee for response within a period of two (2) months pursuant to Section 1.136(a) in the amount of **\$420.00** in accordance with Section 1.17 is enclosed herewith.

Applicants have already paid for the fourth independent claim. However, the fee for three (3) claims over twenty (20) in the amount of **\$54.00** is also enclosed herewith.

Applic. No. 10/010,246
Response Dated April 2, 2004
Responsive to Office Action of November 26, 2003

Please charge any other fees that might be due with respect to
Sections 1.16 and 1.17 to the Deposit Account of Lerner and
Greenberg, P.A., No. 12-1099.

Respectfully submitted,



For Applicants

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